

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 758555C	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/AU2007/001188	International filing date (<i>day/month/year</i>) 20 August 2007	Priority date (<i>day/month/year</i>) 21 August 2006	
International Patent Classification (IPC) or national classification and IPC Int. Cl. A61M 1/12 (2006.01) A61B 17/12 (2006.01)			
Applicant SUNSHINE HEART COMPANY PTY LTD et al			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of 2 sheets, as follows:</p> <div style="margin-left: 40px;"> <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. </div> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																									
<p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>		<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
<input checked="" type="checkbox"/>	Box No. I	Basis of the report																							
<input type="checkbox"/>	Box No. II	Priority																							
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability																							
<input checked="" type="checkbox"/>	Box No. IV	Lack of unity of invention																							
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																							
<input type="checkbox"/>	Box No. VI	Certain documents cited																							
<input type="checkbox"/>	Box No. VII	Certain defects in the international application																							
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application																							

Date of submission of the demand 11 February 2008	Date of completion of this report 11 March 2008
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. +61 2 6283 7999	Authorized Officer EMMA FRANCIS AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. (02) 6283 2667

Box No. I **Basis of the report**1. With regard to the **language**, this report is based on:

- ☒ The international application in the language in which it was filed
- ☐ A translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3(a) and 23.1 (b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):☐ the international application as originally filed/furnished☒ the description:pages **1-12** as originally filed/furnished

pages* received by this Authority on _____ with the letter of

pages* received by this Authority on _____ with the letter of

☒ the claims:

pages as originally filed/furnished

pages* as amended (together with any statement) under Article 19

pages* **13-14** received by this Authority on **11 February 2008** with the letter of the same

pages* received by this Authority on _____ with the letter of

☒ the drawings:

pages as originally filed/furnished

pages* **1/8-8/8** received by this Authority on **5 November 2008** with the letter of the same

pages* received by this Authority on _____ with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to the sequence listing (*specify*):

5. ☐ This report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to the Authority under Rule 91 (Rule 70.2(e)).

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation to restrict or pay additional fees the applicant has, within the applicable time limit:
- ☐ restricted the claims
 - ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☐ neither restricted the claims nor paid additional fees
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☐ complied with.
 - ☒ not complied with for the following reasons:
[See supplemental sheet]
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos.

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1-9	YES
	Claims	NO
Inventive step (IS)	Claims 1-9	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-9	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

The following documents were cited in the International Search Report :

D1: WO 2005/041783 (12 May 2005)

D2: US 6626821 (30 September 2003)

D3: US 6616596 (9 September 2003)

D4: US 4957477 (18 September 1990)

D5: US 6808483 (26 October 2004)

D6: WO 2005/110512 (24 November 2005)

The present application defines a flexible wrap used to hold an inflatable chamber against a curved arterial vessel, preferably the heart, which has a curved shape when laid out on a flat surface.

Novelty (N) and Inventive Step (IS)

D1 forms part of the applicants prior art and is the basis for the improvement discussed in the current application. It defines a flexible wrap used to hold an inflatable device against an arterial vessel with two slits formed at the centre of the wrap.

D2 discloses a cardiac wrap comprising a material covering applied around either the left or right ventricles and further includes a series of inflatable elements which are used to provide active assistance.

D3 discloses a heart assist system comprising a series of inflatable tube pairs which wrap around the heart to approximate the myocardium, bound in place using a sheath.

D4 discloses a heart assist device comprising a double walled jacket adapted to enclose at least the ventricular portion of the heart. The space between the two walls may be filled with a fluid which is easily displaceable.

D5 discloses a heart assist device comprising both a passive (mesh or webbing) and an active assistance member (fluid inflatable member).

D6 discloses an inflatable device used as an epicardial support comprising a double walled membrane whereby the cavity between the two walls can be inflated through the use of a fluid and a pump.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX IV

This International Preliminary Examination Authority has found that there are different inventions as follows;

- Claims 1-4 define a flexible wrap designed to hold an inflatable chamber or balloon against the outside surface of a curved vessel. It is considered that the intermediate portion comprising three side by side portions whereby the outer portions are longer than the central portion comprises a first special technical feature.
- Claims 5-9 define a flexible wrap designed to hold an inflatable chamber or balloon against the outside surface of a curved vessel. It is considered that the wrap when positioned flat on a surface includes a dome like portion comprises a second special technical feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence defines a special technical feature as a feature which makes a contribution over the prior art.

The only feature in common to all of the claims is a flexible wrap designed to hold an inflatable chamber against the outside surface of a curved vessel. However this concept is not novel in light of the prior art cited in the ISR, for example WO 2005/041783 (12 May 2005) the applicants own application.

This means that the common feature can not constitute a special technical feature within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art.

Because the common feature does not satisfy the requirement for being a special technical feature it follows that it cannot provide the necessary technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention, *a posteriori*.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V

However there is no disclosure in any of these documents of a dome like portion formed when the wrap is laid out flat or a wrap comprising three elongate portions and as such the subject matter of these claims is new and meets the requirements of Article 33(2) of the PCT with regard to novelty. These claims are also considered to involve an inventive step.

Industrial Applicability (IA)

The invention defined in the claims is considered to meet the requirements of Industrial Applicability under Article 33(4) of the PCT because it can be made by, or used in, industry.

Claims

1. In a heart assist device in which an inflatable balloon or chamber is held against an outside surface of a curved arterial vessel by a wrap formed from a flexible sheet-like material, the wrap having a first end portion, a second end portion and an intermediate portion connecting together the first and second end portions, the intermediate portion comprising at least three separate elongate sections arranged in side by side array each connected at each end to a respective one of the end portions of the wrap, the improvement in that the laterally outer ones of the elongate sections are longer than the central one of them.
2. In a heart assist device in which an inflatable balloon or chamber is held against an outside surface of a curved arterial vessel by a wrap formed from a flexible sheet-like material, the wrap having an inside surface and an outside surface and having a first end portion, a second end portion and an intermediate portion connecting together the first and second end portions, the intermediate portion comprising at least three separate elongate sections arranged in side by side array each connected at each end to a respective one of the end portions of the wrap, the improvement in that the laterally outer ones of the elongate sections are longer than the central one of them.
3. The heart assist device as claimed in claim 2, wherein the laterally outer edges of the longitudinally outer ones of the elongate sections are longer than the laterally inner edges of the respective elongate sections.
4. The heart assist device as claimed in claim 1, 2 or 3, wherein the three elongate sections each have a longitudinal axis and the axes of the two laterally outer elongate sections diverge from one another and from the central elongate section along their length from substantially a mid point of the intermediate portion to each of the end portions.
5. In a heart assist device in which an inflatable balloon or chamber is held against an outside surface of a curved arterial vessel by a wrap formed from a flexible sheet-like material, the improvement whereby if the wrap were laid on a planar surface it would include a dome-like portion extending away from that surface.

6. The heart assist device as claimed in claim 5, wherein the dome-like shape is at least partially formed by heat setting of the sheet-like material adjacent an end of the wrap.
- 5 7. The heart assist device as claimed in claim 6, wherein the heat setting of the sheet-like material is between corresponding convexly and concavely shaped mould surfaces.
8. The heart assist device as claimed in claim 7, wherein the dome-like shape is at least partially formed by removing substantially triangular sections of the material and
10 then joining edges of the material the adjacent removed portions.
9. The heart assist device as claimed in claim 7, wherein the dome-like shape is at least partially formed by removing substantially triangular sections of the material and then joining edges of the material the adjacent removed portions by gluing and/or
15 suturing.